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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,111	02/20/2002	Susan G. Stuart	PC-0053 CIP	6385

27904 7590 10/15/2004

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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/079,111		STUART ET AL.	
	Examiner		Art Unit	
	Juliet C. Switzer		1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/02</u> . | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment</u> . |

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-6 in the reply filed on 9/1/04 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to search the polypeptides of invention II. This is not found persuasive because the search of polynucleotides and polypeptides are not coextensive. The inventions of groups I and IV have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases, which differ for polynucleotides and polypeptides. There is a further search burden because there may have been "classical" genetics papers which had no knowledge of the polypeptide but teach the gene. Similarly, prior to the concomitant isolation and expression of the sequence of interest there may journal articles devoted solely to polypeptides which would not have described the polynucleotides. Searching, therefore, is not coextensive. In addition, the claims identify both the polynucleotides and the claimed polypeptides via homology language. For example, group I includes claims that encompass polynucleotides that do not encode the polypeptide of SEQ ID NO: 1 (i.e. polynucleotides that have at least 85% identity to SEQ ID NO: 2). This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of the nucleic acids claims extend beyond those that encode the claimed polypeptides. Thus, for all of these reasons, it would be burdensome to search the inventions of groups I and IV together.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. The instant application claims priority as a CIP to application serial number 09/232160 filed January 15, 1999 and issued as US 6368794 B1. The claims of the instant application are not granted priority to the parent application because the prior application does not provide support for the instant claims for at least the following reasons:

(A) There is no basis in the parent application for the language “at least 90% sequence identity” as recited in claim 1(c) or for the language “at least 85% sequence identity” as recited in claim 2(b). The specification and originally filed claims of the parent application were reviewed for basis for these limitations and none was located.

(B) The parent application does not provide sufficient guidance to enable one to use the instantly claimed invention. The parent application teaches an isolated nucleic acid (SEQ ID NO: 13) therein encoding a polypeptide (SEQ ID NO: 21 therein) that are identical to SEQ ID NO: 2 and SEQ ID NO: 1, respectively, of the instant application. Regarding all of the sequences disclosed in the parent application, the specification of the parent application teaches that all of them had expression levels in the diseased samples that “was at least 2-fold higher or 2-fold lower than their expression level in the non-diseased samples (referring to Col. 19, lines 45-50 of the issued patent).” The specification of the parent application discloses that SEQ ID NO: 13 of that application was isolated from library HEAANOT01 (Table 1, Col. 20). The specification of the parent application does not disclose which disease this molecule was over or under expressed in, it does not teach whether the diagnostic/prognostic expression was over or under expression, it does not give any guidance as to how to use this sequence in an assay to predict a predisposition to cancer or any other disease. The specification of the parent

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application does not provide any working examples wherein SEQ ID NO: 13 is used for any diagnostic purpose. It would be highly unpredictable as to what disease could be detected, or what level of expression is indicative of the disease state. In order to utilize the instantly claimed invention based on the disclosure of the parent application, one would be required to undertake extensive experimentation screening of tissue samples from any and/or all cancers in order to establish that the instantly claimed molecules are useful for the diagnosis or prognosis of any cancer. The teachings of the parent application are an invitation to undertake further experimentation to determine how to utilize the instantly claimed invention. Therefore, for this reason as well, priority to the parent application is not granted.

3. The filing date of the instantly pending claims is therefore 2/20/02.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Lai *et al.* (WO 00/00610).

This reference is available as a 102(b) type reference because priority was not granted to the parent application for the instant claims. In the event that applicant is able to establish

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priority to the parent application for the claimed invention, rejections in view of this reference will be withdrawn.

Lai *et al.* teach an isolated nucleic acid sequence encoding instant SEQ ID NO: 1.

Lai *et al.* teach an isolated nucleic acid sequence that comprises instant SEQ ID NO: 2.

Namely, nucleotides 1-2029 of instant SEQ ID NO: 2, which encodes instant SEQ ID NO: 1, are identical to nucleotides 1-2029 of SEQ ID NO: 198 taught by Lai *et al.*

With regard to claim 3, Lai *et al.* teach compositions which comprise a labeling moiety (see p. 56, line 31).

With regard to claim 4, Lai *et al.* teach an expression vector comprising their SEQ ID NO: 198 (see p. 157, claim 12).

With regard to claim 5, Lai *et al.* teach a host cell comprising the vector (see p. 157, claim 13).

With regard to claim 6, Lai *et al.* teach a method for producing a polypeptide which includes culturing the host cell and isolating the polypeptide (see p. 157, claim 14).

Therefore, the instant claims are all anticipated by the teachings of Lai *et al.*

6. Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by the GenBank Record H69328 (GI: 1039534; October 24, 1995).

The GenBank record teaches an isolated cDNA comprising a nucleic acid sequence encoding an immunogenic fragment of SEQ ID NO: 1. Namely, nucleotides 1-342 of the GenBank record encode amino acids 142-255 of instant SEQ ID NO: 1. This fragment would be sufficient to raise an antibody, and thus is considered an immunogenic fragment.

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With regard to claims 4 and 5, the record teaches that the sequence is within a vector pT7T3D and the vector is within the host cell DH10B (see "source" description in record).

Therefore, the teachings of the GenBank record anticipate claims 1, 4, and 5.

7. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni *et al.* (US 5942417).

Ni *et al.* teach an isolated cDNA comprising a nucleic acid sequence encoding a variant of sid 1 having at least 90% sequence identity to SEQ ID NO: 1, and comprising a variant of SEQ ID NO: 2 having at least 85% identity to SEQ ID NO: 2.

Namely, nucleotides 91-1056 of SEQ ID NO: 1 taught by Ni *et al.* encodes a polypeptide that is 99.69% identical to instant SEQ ID NO: 1. The encoded polypeptide taught by Ni *et al.* differs from instant SEQ ID NO: 1 by a single amino acid at position 83 of instant SEQ ID NO: 1. Nucleotides 6-1993 of SEQ ID NO: 1 taught by Ni *et al.* are 99.6% identical to nucleotides 98-2025 of instant SEQ ID NO: 1. An alignment of instant SEQ ID NO: 1 against SEQ ID NO: 1 taught by Ni *et al.* is enclosed with this office action.

With regard to claim 3, Ni *et al.* teach the molecule with a label moiety (Col. 24, lines 9-10).

With regard to claims 4, 5 and 6, Ni *et al.* teach the molecule within a vector and host cell (Col. 3, lines 32-37; Col. 12-15) and a method for using the cDNA to produce a protein comprising culturing the host cell and recovering the host cell from culture (Col. 15, line 63-Col. 16, line 4).

Therefore, the teachings of Ni *et al.* anticipate all of the rejected claims.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to isolated cDNA molecules which comprise nucleic acid sequences encoding an immunogenic fragment of SEQ ID NO: 1 or a variant of SEQ ID NO: 1 having 90% sequence identity to SEQ ID NO: 1 and to isolated cDNA molecules wthi comprise a variant of SEQ ID NO: 2 having at least 85% identity to SEQ ID NO: 2.

The specification teaches a nucleic acid molecule comprising a full length open reading frame which encodes the polypeptide of SEQ ID NO: 2. The specification does not provide any additional variants or homologues of SEQ ID NO: 1 or SEQ ID NO: 2, as are encompassed by the instant claims. Furthermore, the instant claims encompass nucleic acids that encode fragments of SEQ ID NO: 1 of any length that is sufficient to raise an antibody within any context due to the combination of the “comprising” language with the fragment language of claim 1. The specification has not demonstrated possession of this wide variety of nucleic acid sequences, having only given a single example of a nucleic acid sequence which encodes a single open reading frame.

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With regard to the written description, all of these claims encompass nucleic acid sequences or constructs comprising these sequences that are different from those disclosed in the specific SEQ ID NO:s. The claims include modifications by permitted by the % identity language for which no written description is provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acid sequence of the disclosed SEQ ID NO and encoding the single described amino acid sequence are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acid encoding a polypeptide modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID No: 2 but possessing one or more amino acid differences such that a different amino acid sequence is encoded which retains the functionality of the disclosed nucleic acid which is expressed in breast tissue that is associated with disease of the breast (i.e. cancer and hyperplasia) but that is not expressed in healthy breast tissue.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6368794. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued patent anticipate instant claims 1 and 2 of the instant invention. Instant SEQ ID NO: 2 is identical to SEQ ID NO: 13 of the issued patent. The claims of the issued patent do not teach vectors, host cells, and methods of protein production, but it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included the cDNA provided in the claims of the issued patent in any of these constructs or for use in these methods as these were methodologies routinely used in the art at the time the invention was made for the production of a protein, for example.

Conclusion

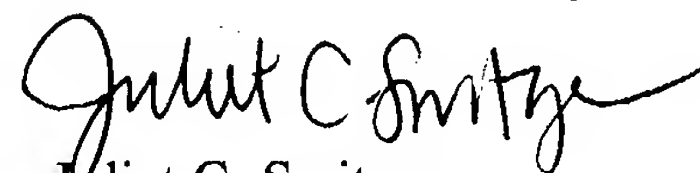
12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached by calling (571) 272-0782.

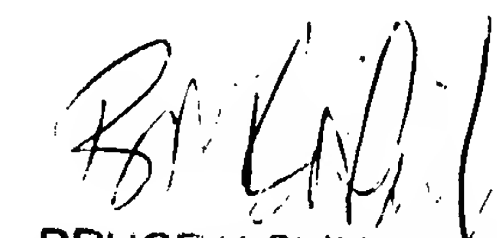
The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Juliet C. Switzer
Examiner
Art Unit 1634

October 11, 2004


BRUCE KISLIUK, DIRECTOR
TECHNOLOGY CENTER 1600

Sequence alignment

instant Seq ID NO:2
VS Seq ID NO: 1 from
Ni et al.

Instant Seq ID NO:2 = Qy
Seq ID NO: 1 from Ni et al. = Db

RESULT 7
US-08-892-880-1
; Sequence 1, Application US/08892880
; Patent No. 5942417
; GENERAL INFORMATION:
; APPLICANT: NI, JIAN
; APPLICANT: GENTZ, REINER L.

```

; APPLICANT: DILLON, PATRICK J.
; TITLE OF INVENTION: CD44-LIKE PROTEIN
; NUMBER OF SEQUENCES: 15
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
; STREET: 1100 NEW YORK AVENUE, NW, SUITE 600
; CITY: WASHINGTON
; STATE: DC
; COUNTRY: USA
; ZIP: 20005-3934
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.30
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/892,880
; FILING DATE: HEREWITH
; CLASSIFICATION: 435
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: 60/021,762
; FILING DATE: 15-JUL-1996
; ATTORNEY/AGENT INFORMATION:
; NAME: STEEFE, ERIC K
; REGISTRATION NUMBER: 36,688
; REFERENCE/DOCKET NUMBER: 1488.0490001
; TELEPHONE: 202-371-2600
; TELEFAX: 202-371-2540
; INFORMATION FOR SEQ ID NO: 1:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 2313 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; MOLECULE TYPE: DNA (genomic)
; FEATURE:
; NAME/KEY: CDS
; LOCATION: 91..1056
; FEATURE:
; NAME/KEY: mat_peptide
; LOCATION: 154..1056
; FEATURE:
; NAME/KEY: sig_peptide
; LOCATION: 91..153
;
us-08-892-880-1
;
Query Match          94.4%; Score 1915.2; DB 2; Length 2313;
Best Local Similarity 99.6%; Pred. No. 0;
Matches 1920; Conservative 0; Mismatches 8; Indels 0; Gaps 0;

Qy      98 CATCCGACTAGTATTGAGCATCTGCTCTCATATGACCAAGTGCCCATCTGAGGTGTT 157
Db      6 CATCCGACTAGTATTGAGCATCTGCTCTCATATGACCAAGTGCCCATCTGAGGTGTT 65

Qy      158 CCCTGGCTCTGAAGGGTAGGCACGATGCGCAGGTGCTTCAGCCTGTGTTGCTTCTCAC 217
Db      66 CCCTGGCTCTGAAGGGTAGGCACGATGCGCAGGTGCTTCAGCCTGTGTTGCTTCTCAC 125

Qy      218 TTCCATCTGACACGAGGCTCCTGTGTCAGAGGCTCTTTGCGTGACAGAGCTTTCCAT 277
Db      126 TTCCATCTGACACGAGGCTCCTGTGTCAGAGGCTCTTTGCGTGACAGAGCTTTCCAT 185

Qy      278 CCAGGTGTCATGCAGAAATTATGGGGATCACCCCTGTGTGAGCAAAAAGGCGAACCAGCAGCT 337
Db      186 CCAGGTGTCATGCAGAAATTATGGGGATCACCCCTGTGTGAGCAAAAAGGCGAACCAGCAGCT 245

Qy      338 GAATTTCACAGAAGCTTAAGAGGCGCTGTAGGCTGTGGGACTAAGTTTGGCCGCAAGGA 397
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Qy      398 CCAAGTTGAACACAGCCTTGAAGGCTAGCTTTGAAACTTGACGCTATGCGTGGTTGAGA 457
Db
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QY 1238 AGAACCAAGAGAAAGTCCACCTTGGTTCTTAATGGAATCAGCTCAGAGTGCATTT 1297
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QY 1538 GACCAAGGCTTTCTCTAATGATTCGCGAGCTCAGACCCCTTCTCTGAGCTCTGAAGAAGAA 1597
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Db 1746 CACACACTTACTTTTCTGCTCTCTACCACTGCTGATATTTCTCTAGGAATATACTTT 1805
QY 1898 TACAGTAAACAAAAATAAAACTCTTATTAATTTCTATTTTCTGAGTTACAGAAATG 1957
Db 1806 TACAGTAAACAAAAATAAAACTCTTATTAATTTCTATTTTCTGAGTTACAGAAATG 1865
QY 1958 ATTACTAAGAAAGATTACTGATTAATTGTTTAAAAAGTAAATAATTCACCAAAACATTT 2017
Db 1866 ATTACTAAGAAAGATTACTGATTAATTGTTTAAAAAGTAAATAATTCACCAAAACATTT 1925
QY 2018 AAAAAAA 2025
Db 1926 GCTGAATA 1933